costs across hernia repair and mesh type cohorts are also presented. **RESULTS:** Across treatment groups the majority of patients were white (~70%) with a mean age of 54 years. Inguinal and umbilical hernia repair groups were both predominantly male with low to moderate incidences of obesity and diabetes. Incisional hernia repair patients had the highest incidence of obesity (19.0%) and diabetes (18.5%) and could be equally either male (42.0%) or female (58.0%). Tissue-separating mesh (TSM) was used mainly in incisional hernia repairs, whilst other meshes were used in all surgical cohorts. TSM was used more frequently in females (60.1%) and in patients with a high incidence of obesity (22.7%) and diabetes (22.1%). No striking differences in surgical costs across the hernia repair or mesh type cohorts were observed, with average surgical costs between $2199 and $4099. **CONCLUSIONS:** This is the first example of extracting hernia repair patient demographics from a nationwide database. Although there are limitations to the interpretation of this data, these results are encouraging. Further development of the management, analysis and interpretation of such data is ongoing.

PMD81

DECISION ANALYTIC MODELS USED IN ESTIMATING THE COST-EFFECTIVENESS OF DRUG-ELUTING STENTS VERSUS BARE-METAL STENTS

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OBJECTIVES: Drug-eluting stents (DES) and bare-metal stents (BMS) are both used widely in percutaneous coronary interventions (PCI). However, the incremental cost-effectiveness of DES versus BMS varies considerably between studies. A systematic review is performed to gain insight how modeling influences the cost-effectiveness of DES versus BMS. **METHODS:** We reviewed modeling studies published until February 2011 that studied the cost-effectiveness of DES versus BMS. We then extracted various parameters (e.g., model type, time horizon, data sources, choice of disease states) and explored the influence of these parameters on the cost-effectiveness outcomes. **RESULTS:** The incremental cost-effectiveness ratios (ICER) from the 22 eligible studies ranged from DES being dominated by BMS to DES being dominant. Different parameters can contribute to these differences, including time horizon, assumptions concerning stent efficacy, study perspective, stent cost prices and the specific type of stents being compared. Almost half of the studies used a time horizon ≤12 months, assuming that differences in clinical events between the two stents occur in the first year. However, published literature contradicts this assumption since DES can induce very late in-stent thrombosis. Moreover, many studies base restenosis rates on angiographic follow-up. Since angiography overestimates the difference in restenosis rate between DES and BMS, its use leads to an overestimate of quality-adjusted life-years gained and number of avoided reinterventions and an underestimate of the costs of the DES strategy. The price premium of DES versus BMS differs considerably between studies (€900-€3300) and this difference also affects the ICER. **CONCLUSIONS:** Choices made in cost-effectiveness models to compare DES with BMS lead to wide variation in cost-effectiveness estimates, making it difficult to conclude that DES is more cost-effective than BMS. Since 80,000 PCIs are performed per year in the UK, it is very important to obtain valid estimates of the cost-effectiveness of DES versus BMS.

PMD82

DRUG ELUTING BALLOON FOR THE TREATMENT OF PERIPHERAL ARTERY DISEASE: A COST-EFFECTIVENESS ANALYSIS IN ITALY

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OBJECTIVES: Conventional balloon angioplasty for treatment of femoropopliteal arterial disease is associated with a high restenosis rates 12 months post-procedure. Recent clinical data have showed that use of DEBs may substantially reduce restenosis. This suggests that DEB may decrease number of revascularizations and therefore be a cost-effectiveness treatment for peripheral artery disease (PAD). This study evaluated the economic impact of using a drug-eluting balloon (DEB) for treatment of femoropoliteal arterial disease. **METHODS:** A decisional tree model has been developed to compare two alternative treatment strategies for superficial femoral artery disease (SFA): standard balloon angioplasty (PTA) and provisional stenting versus DEB. Cost for initial hospital care and the long term management of the disease, including reintervention, has been accounted for according to National Health Care Service and societal perspectives. Probabilities have been retrieved by available literature review of RCT and from an observational study on DEB that evaluated risk of target lesion revascularization (TLR) at 1 year. Uncertainty around the model inputs was tested using unvaried and multivariate sensitivity analyses **RESULTS:** Specific procedure costs (including angioplasty balloon, DEB, stent, contrast medium) were 1500€ in both group because incremental cost for use of DEB was offset by reduction of number of stents used in the DEB arm. No difference has been noted also for initial hospitalization. Given a 1 year TLR rate of 8.7% and 14% for DEB and stenting respectively, DEB resulted a cost-saving strategy for the treatment of superficial femoral artery disease. Results were sensitive to hypothesis on number of stents and DEB used and their relative cost. **CONCLUSIONS:** PTA of femoropopliteal arterial disease using DEB appears to be a clinical improvement for treatment of PAD and a potentially cost saving strategy compared to use of stents in the Italian Health Care System.

PMD83

USING FIVE EXISTING MODELS TO COMPREHENSIVELY MODEL THE COST-EFFECTIVENESS OF A HIGH DEFINITION CT SCANNER IN A CORONARY ARTERY DISEASE POPULATION: A NICE DIAGNOSTIC GUIDANCE PROJECT

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OBJECTIVES: Cost-effectiveness analysis (CEA) of a medical test can require extensive modeling if test results influence treatment decisions and disease progression. We applied the assessment hierarchy of Schaafsma et al. (2009) to a CEA of a high definition CT-scanner (one of the first assessments in the NICE/UK Diagnostics Guidance Programme). **METHODS:** Schaafsma presents four steps to evaluate the value of diagnostic tests: 1:accuracy assessment, 2:evaluation of added value, 3:clinical outcome assessment and 4:cost-effectiveness analysis. **RESULTS:** In the assessment of diagnostic tests in coronary artery disease (CAD) modeling was unavoidable, since a major problem in CEAs is the unavailability of randomized controlled trials (RCT) that capture diagnosis, prognosis and treatment. Moreover, most RCTs in the field of diagnostic test yield only information about sensitivity, specificity, and short-term complication rates. When the evaluation is limited to the added value of the high definition CT-scanner, one model, estimating the proportions correctly diagnosed and complications associated with the CT-scanner, is sufficient. However, since incorrect test results can result in major health loss through incorrect or delayed treatment this method is inappropriate. Most tests aim to improve prognosis thus, step 3 and 4 were applied in our assessment. Therefore, five existing models were combined (diagnosis, CAD management, stroke complication, radiation, non-CAD mortality) to create a meta-model that estimates the cost-effectiveness. **CONCLUSIONS:** CEAs of a medical test can be performed in various ways described by Schaafsma. If the aim is to conduct a comprehensive analysis that includes various economic and health impacts, a synthesis of existing models to create a meta-model is one way to achieve this. These models need to be grafted together carefully to avoid invalid or irrelevant results; literature and expert opinion can assist in that endeavour. One critical pitfall is the use of models created for dissimilar patient populations.

PMD84

ASSESSING COST EFFECTIVENESS AND VALUE OF FURTHER RESEARCH WHEN DATA ARE SPARSE: NEGATIVE PRESSURE WOUND THERAPY FOR SEVERE PRESSURE ULCERS

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OBJECTIVES: Health care resources are scarce and decisions have to be made about how to allocate funds. Often these decisions are based on sparse or imperfect evidence. One such example is negative pressure wound therapy (NPWT), which is a widely used treatment for severe pressure ulcers; however, there is currently no robust evidence that it is effective or cost effective. **METHODS:** This work considers the decision to adopt NPWT given a range of alternative treatments, using a decision analytic modelling approach. Literature searches were conducted to identify existing evidence on model parameters. Given the limited evidence base, a second source of evidence, beliefs elicited from experts, was used. Judgements from experts on relevant (uncertain) quantities were obtained through a formal elicitation exercise. Additionally, data derived from a pilot trial were also used to inform the model. The three sources of evidence were collated, and the impact of each on cost effectiveness was evaluated. **RESULTS:** Negative pressure wound therapy was expected to be less costly and more effective than any other treatments. The decision to adopt NPWT was however very uncertain (probability of being cost effective of 0.55). The expected value of perfect information for the relevant UK population was approximately £98 million. Specifically, the results suggest that a study evaluating the effectiveness of NPWT might be worthwhile. The trial design that offered most value was a three armed trial, with follow-up of at least 1 year and approximately 500 participants per arm. **CONCLUSIONS:** The analyses presented demonstrate how allocation decisions about medical technologies can be explicitly informed when data are sparse and, how this kind of analyses can be used to guide future research prioritisation, not only indicating whether further research is worthwhile but what type of research is needed and how it should be designed.

PMD85

SLEEP QUESTIONNAIRES DISCRIMINATE BETWEEN PARTICIPANTS WITH AND WITHOUT OVERACTIVE BLADDER SYMPTOMS

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OBJECTIVES: Nighttime urinary frequency (nocturia), common in patients with overactive bladder (OAB), negatively impacts sleep quality. Three sleep-related patient-reported questionnaires were assessed with regard to ability to discriminate between patients with and without OAB. **METHODS:** Adult men and women with OAB symptoms for at least 3 months (≥8 micturitions per day; ≥2 micturitions per night; and ≥6 urgency episodes over 3 days per bladder diary) and without OAB symptoms (control group) completed several sleep questionnaires: Stanford Sleepiness Scale (morning and evening for 5 days), Epworth Sleepiness Scale, and Nocturia Quality of Life Questionnaire (N-QoL); t tests were performed between groups. **RESULTS:** A total of 43 participants with OAB and 10 healthy controls were enrolled. Mean age and proportion of men were similar in the OAB and control groups (63.7 vs. 55.6 years old [P=0.31], and 46.2% vs 40.0% male [P=0.53], respectively). Race, employment status, and education level were also similar between groups (all P>0.25). Mean scores on the Stanford Sleepiness Scale across the 5 days were significantly higher in the OAB group than the control group at time of awakening (3.0 vs. 2.0; P=0.0030) and at 7:00 pm (3.5 vs. 1.9; P=0.0006), indicating greater sleepiness. Epworth Sleepiness Scale mean scores were also significantly higher in the OAB group than the control group (10.5 vs 4.1, respectively; P<0.0001), indicating greater daytime sleepiness. On the N-QoL, participants with OAB had signifi-

cantly lower mean Total scores than controls (54.7 vs. 99.2; P<0.0001), Sleep/energy scores (55.9 vs. 100.0; P<0.0001), and Bother/concern scores (54.0 vs. 98.3; P<0.0001), indicating greater health-related quality of life impairment because of nighttime urination. **CONCLUSIONS:** The Stanford Sleepiness Scale, Epworth Sleepiness Scale, and N-QoL all effectively discriminate between participants with OAB symptoms and those without OAB symptoms.

PMD86

A SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS CONDUCTED FOR ASSESSMENT OF GENETIC TESTING TECHNOLOGIES

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OBJECTIVES: The conventional economic evaluations (EE) methods may be challenging within the context of genetic testing technologies (GTTs), because: the main outcome a GTT is information, benefits may occur many years after taking the test, non-medical harms might be associated with GTTs, and GTTs may also provide information about the genetic status of the family members of affected individuals. This study was performed to systematically review the methods used in EEs included in Health Technology Assessments (HTAs) of GTTs. **METHODS:** A systematic search of literature was undertaken to identify HTA reports on GTTs that included EEs in addition to clinical effectiveness results. Studies were reviewed in terms of methods (e.g. type of EE, analytic perspective, cost-effectiveness analysis), and quality (using QHES instrument). **RESULTS:** Of 342 identified citations, 13 HTAs consisting of 10 model-based and 3 trial-based EEs were included. More than 50% of the included studies had moderate to low quality scores mainly due to not reporting information on basic elements of a standard EE and inadequate management of uncertainty. Cost-effectiveness analysis (CEA) accounted for 62% of included studies. 65% of the studies adopted a third party payer perspective, and 60% used a lifelong time horizon. 75% of CEAs reported intermediate outcomes (e.g. cases-detected). The majority of studies exclusively included technical costs of testing (100%) and therapeutic or preventive interventions (62%). The most frequent variables tested in univariate sensitivity analysis included costs (62%), effects (46%) and transition probabilities (54%). Probabilistic sensitivity analysis was conducted in 31% of studies. **CONCLUSIONS:** We found several methodological challenges in the reviewed EEs, including: identification of a proper analytical perspective, inclusion of wider range of outcomes and costs, allowing for long-term psychological, ethical and social impacts of genetic tests, and sufficient management of uncertainty. These issues should be carefully considered in future EEs of GTTs.

Surgery – Clinical Outcomes Studies

PSU1

SUPRAPUBIC TUBE PLACEMENT RELATED BOWEL INJURY: PROPOSED GUIDELINES FOR OPEN PLACEMENT

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OBJECTIVES: Suprapubic catheterization (SPT) is a common urologic procedure performed on an elective and urgent basis. Percutaneous approaches have developed in an effort to circumvent the need for general/spinal anesthesia, but are not without risk. Rates of SPT-related bowel injury range from 0.3% to 2.7%. We experienced 4 cases and reviewed the literature to determine identifiable risk factors for bowel injury. **METHODS:** A literature review was performed of all English language articles listed in PubMed and articles reporting percutaneous SPT placement related bowel injury were selected. Included in our review are 4 cases in our institution. Data from articles and our cases was extracted to determine the technique of SPT placement utilized, underlying risk factors, and nature of bowel injury. **RESULTS:** Nineteen papers reported 22 cases of bowel injury as a result of percutaneous SPT placement, 2 of which were excluded for insufficient data. Additionally, the 4 cases at our institution were included in the analysis. Small capacity or thick-walled neurogenic bladders (4/24, 17%), prior abdominal surgery (13/24, 54%), and pelvic radiation (5/24, 21%) were associated with bowel injury during SPT placement. Diagnosis of bowel injury was based on history, physical examination and imaging modalities. Bowel injury had a bimodal presentation, at initial placement (14/24, 58%) and at initial SPT change (10/24, 42%). **CONCLUSIONS:** Based on this review we advocate consideration of open SPT placement in patients with small capacity or thick-walled neurogenic bladders, those in whom the bladder cannot be distended adequately, prior abdominal/pelvic surgery or radiation, ascites. If percutaneous SPT is planned, Trendelenburg positioning and use of ultrasound and/or fluoroscopy at time of SPT placement is supported by the literature.

PSU2

COMPARISON OF SEIZURE AND HYDROCEPHALUS AND OTHER CLINICAL CONDITIONS BEFORE AND AFTER SUBEPENDYMAL GIANT CELL ASTROCYTOMA SURGERY IN PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX

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OBJECTIVES: To compare the prevalence rates of seizure, hydrocephalus and other clinical conditions before and after a surgical removal of subependymal giant cell astrocytoma (SEGA) in patients with tuberous sclerosis complex (TSC). **METHODS:** A pre-post comparative longitudinal cohort study was conducted based on 3 large US national healthcare claims databases (2000-2009). TSC patients with a first observed SEGA surgery at age 35 or younger and with continuous health insurance coverage 1 year before and 1 year after the surgery were selected. The prevalence rates of seizure, hydrocephalus, and other TSC related clinical conditions, such as vision disorders, coma, speechlessness, headache, stroke or hemiparesis, cognitive difficulties, muscle weakness, papillodema, balance disorders, loss of sensation, nausea and vomiting, depression, anxiety, attention deficit disorders, autism, and sleep disorders, were estimated and compared between a period of the last 6 preoperative months and the first two postoperative periods (the 2nd to 6th postoperative months; 7th to 12th postoperative months). Repeated measures analysis with bootstrapping re-sampling approach was used for the cross-period comparisons. **RESULTS:** The mean age of the select patients (N=47) was 11.6 year at their first observed SEGA surgery; the majority of the patients were male (66%). Statistically significant postoperative increases in the prevalence rates of seizure (23~ 26%, p<0.05), hydrocephalus (21~26%, p<0.05), headache (17~19%, p<0.05), stroke and hemiparesis (6~9%, p<0.05), and autism (9%, p<0.05) were observed. **CONCLUSIONS:** This real-world claim data showed an increase in the risk of some clinical conditions including seizure and hydrocephalus after a SEGA surgery in patients with TSC. Further research to explore any possible causal relationship between these risk increases and SEGA surgery through prospective studies or registries is needed.

PSU3

PREVALENCE RATES OF SURGICAL COMPLICATIONS AMONG TUBEROUS SCLEROSIS COMPLEX PATIENTS WITH SURGICAL REMOVAL OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA: A REAL-WORLD NATIONAL RETROSPECTIVE COHORT STUDY

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OBJECTIVES: To examine the prevalence rates of surgical complications among tuberous sclerosis complex (TSC) patients with surgical removal of subpendymal giant cell astrocytoma (SEGA). **METHODS:** Based on 3 US national health care claims databases (2000~2009), a retrospective cohort study was conducted in TSC patients who had a SEGA surgery at age 35 or younger, and were under continuous health insurance coverage 1 year before and 1 year after the surgery. A SEGA surgery was identified by a healthcare claim that simultaneously had a TSC diagnosis code, a benign brain tumor diagnosis code and a procedure code of removing a benign tumor from cerebral ventricle system. The surgical complications examined in the study included surgical procedure complications, nervous system complications, surgical misadventures, postoperative infection, subdural empyemas, and epidural abscess. The prevalence rates of these conditions were estimated for the first postoperative year. **RESULTS:** Approximately 47 TSC patients had at least one SEGA surgery. The mean age of patients at their 1st observed SEGA surgery was 11.6 years. The majority of patients (66%) were male. The prevalence rates of surgical complications in the 1st postoperative year were 34% for surgical procedure complications, 17% for subdural empyemas, 12.8% for nervous system complications, 6% for postoperative infection, 2% for epidural abscess, and 0% for surgical misadventures respectively. **CONCLUSIONS:** In this real-world claim database analysis, we observed that a portion of TSC patients experienced surgical complications within first year after their SEGA surgeries. Further research is needed to better understand the causes of this surgical outcome.

PSU4

POSTOPERATIVE PREVALENCE RATE OF SUBEPENDYMAL GIANT CELL ASTROCYTOMA (SEGA) DIAGNOSIS AND REPEATED SEGA SURGERY IN PATIENTS WITH TUBEROUS SCLEROSIS COMPLEX: A REAL-WORLD NATIONAL RETROSPECTIVE COHORT STUDY

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OBJECTIVES: To examine the postoperative prevalence of subependymal giant cell astrocytoma (SEGA) diagnosis and repeated SEGA surgeries among patients with tuberous sclerosis complex (TSC) who had an initial SEGA surgery. **METHODS:** Based on three US national health claims databases (2000~2009), we conducted a retrospective cohort study with TSC patients who had a first observed SEGA surgery at age 35 or younger and were under continuous health insurance coverage 1 year before and 1 year after their 1st SEGA surgery. A SEGA surgery was defined as having 1) a TSC diagnosis code, 2) a benign brain tumor diagnosis code, and 3) a procedure code for removing a benign tumor from cerebral ventricle system. A SEGA diagnosis is defined as 1) and 2). The prevalence rates of postoperative SEGA diagnosis and repeated SEGA surgery were estimated for a period from the 3rd through 6th postoperative month and a period from the 7th through 12th postoperative month respectively. **RESULTS:** The select patients (N=47) had mean age of 11.6 years (at the 1st SEGA surgery) with 66% males. After the 1st observed SEGA surgery, postoperative prevalence rates of SEGA diagnosis was 34% in the period from the 3rd to 6th postoperative month and 26% in the period from the 7th to 12th postoperative month. About 4~9% patients had a repeated SEGA surgery in their 1st postoperative year. **CONCLUSIONS:** In the real-world setting, TSC patients with SEGA surgery may experience repeated SEGA surgeries or/and still have SEGA diagnoses within the first postoperative year. Further research on the effectiveness of SEGA surgery via prospective studies or registries is needed to improve care in TSC patients with SEGA.

PSU5

RISK OF ARTHRITIS AS A PREDICTOR FOR THE MISDIAGNOSIS OF CHONDROLYSIS: AN INTERNATIONAL ANALYSIS OF CLINICAL OUTCOMES

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